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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,756

10/25/2005

David John Haydon

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EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT

PAPER NUMBER

1652

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,756	Applicant(s) HAYDON, DAVID JOHN	
	Examiner IQBAL H. CHOWDHURY	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 11, 14-16 and 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 10 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/05, 6/08, 9/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a 371 of PCT/GB03/05376.

Claims 1-11 and 14-22 are currently pending.

The preliminary amendment filed on 3/25/2009 amending claims 9 and 17 is acknowledged.

Election/Restriction

Applicant's election without traverse of Group III claim(s) 9-10 and 17, drawn to a compound, which impairs 1-phosphatidylinositol-4-phosphate-5-kinase PIP5K or MSS4 function and a composition comprising said MSS4 inhibitor in the communication filed on 3/25/2009 is acknowledged. Claims 1-8, 11, 14-16 and 18-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 9-10 and 17 are present for examination.

Priority

Acknowledgement is made of applicants claim for foreign priority under 35 USC 119(a-d) to UK (GB) 0228706.8 filed on 12/9/2002.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on 9/22/08, 6/17/08 and 9/1/05 are acknowledged. The submission is in compliance with the provisions of 37

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CFR 1.97. Accordingly, the information disclosure statements are considered by the examiner. The signed copies of IDSs are enclosed herewith.

Drawings

Drawings submitted on 6/6/2005 accepted by the examiner.

Objection to Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code (see, page 1-2). See MPEP § 608.01.

Claim Objections

Claim 17 is objected to as depending from non-elected claim. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 9 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9 and 17 are indefinite as

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reciting methods lacking **crucial** steps, i.e. a method step d) that determines if “the candidate compound inhibits said MSS4”.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-10 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 9-10 and 17 are directed to a compound which impairs 1-phosphatidylinositol-4-phosphate-5-kinase (PIP5K) or MSS4 function and a composition comprising said PIP5K or MSS4 inhibitor.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a

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skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (paraphrased from *Enzo Biochemical*).

University of Rochester v. G.D. Searle & Co. (69 USPQ2d 1886 (2004)) specifically points to the applicability of both *Lily* and *Enzo Biochemical* to methods of using products, wherein said products lack adequate written description. While in *University of Rochester v. G.D. Searle & Co.* the methods were held to lack written description because not a single example of the product used in the claimed methods was described, the same analysis applies wherein the product, used in the claimed methods, must have adequate written description (see *Enzo* paraphrase above).

Thus, claims 19-10 and 17 are drawn to any compound which impairs any PIP5K or MSS4 enzyme function or activity and a composition comprising said PIP5K or MSS4 inhibitor. Claims are drawn to any compound and any PIP5K or MSS4 enzyme whose structures are not fully described in the specification. No information, beyond the characterization of a compound that impairs any PIP5K or MSS4 enzyme function or activity has been provided, which would indicate that they had possession of the claimed genus of any compound and any PIP5K or MSS4 enzyme.

The specification does not disclose any inhibitors, which impairs said PIP5K or MSS4 function or activity to be identified as an antifungal compound. There is no description regarding the relationship of structure to function of compound and PIP5K or

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MSS4 enzymes. The specification discloses three representative species of PIP5K or MSS4 enzyme such as PIP5K or MSS4 from *Candida* and *Aspergillus* sp. and the specification does not teach any representative species of compounds which impairs PIP5K or MSS4 function or activity.

Given this lack of description of representative species encompassed by the genus of compounds and PIP5K or MSS4 enzymes, wherein the compound impairs PIP5K or MSS4 function or activity, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 9-10 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an *E. coli* expressing PIP5K or MSS4 gene from *Candida albicans* and yeast *Candida albicans* comprising PIP5K or MSS4 gene under tetracycline regulatable expression system and an assay system for measuring PIP5K or MSS4 activity or function for identifying compound which modulate the activity of said PIP5K or MSS4 enzyme, does not reasonably provide enablement for any compounds which impair any PIP5K or MSS4 enzyme function or activity and a composition comprising said PIP5K or MSS4 inhibitor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Claims 9-10 and 17 are so broad as to encompass any compound which impairs any PIP5K or MSS4 enzyme function or activity and a composition comprising said PIP5K or MSS4 inhibitor.

The specification does not disclose any PIP5K or MSS4 enzyme inhibitors, which impairs PIP5K or MSS4 enzyme activity or function, which can be used as antifungal compound.

Due to the large quantity of experimentation necessary to generate the nearly infinite number of PIP5K or MSS4 enzyme inhibitors and screen same for anti-fungal activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of inhibitor structure and function, and the breadth of the claims which fails to recite any structural limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by

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Miyazaki et al. (Comparison of kinetic properties between MSS4 and Rab3A GRF GDP/GTP exchange proteins, FEBS Lett, 1994 Aug 22;350(2-3):333-6).

Miyazaki et al. teach RabGD1, which is inhibitory of GEP (GDP/GTP exchange protein) inhibits MSS4 (abstract, line 4, page 335, column 1, paragraph 2 and Fig. 4), wherein the assay method comprises contacting RabGD1 with MSS4 (page 334, column 1, paragraph 3), wherein said compound would have inhibitory activity to any MSS4 including fungal MSS4. A composition (claim 10) comprising inhibitor of MSS4 is nothing but the inhibitor of MSS4 itself and a pharmaceutically acceptable carrier can be water or buffer which is taught by Miyazaki et al. Since, Miyazaki et al. teach compound which inhibits MSS4 activity, the same compound would inherently have antifungal activity if the fungus comprises said MSS4 gene encoding protein because MSS4 or PIP5K is regarded as stimulator of cell growth by activating MSS4 or PIP5K activity and thereby an inhibitor of MSS4 or PIP5K would inhibit fungal cell growth. Because the compound of the claimed invention and the corresponding compound of the reference is identical, Examiner takes the position that the compound of the reference inherently have inhibitory to cell growth and viability of the fungal cell comprising fungal MSS4. Since the Office does not have the facilities for examining and comparing applicants' compound with the compound of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

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Besides, the statements of intended use for the claimed compound (as antifungal compound) recited in claims 9 and 17 is noted. However, M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." For purposes of applying prior art, the examiner has thereby disregarded the recited intended uses of the compound in claims 9 and 17.

Conclusion

Status of the claims:

Claims 1-11 and 14-22 are pending.

Claims 1-8, 11, 14-16 and 18-22 are withdrawn.

Claims 9-10 and 17 are rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T Nashed can be reached on 571-272-0934. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, Patent Examiner
Art Unit 1652

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657